UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF ALABAMA

ROMIE HARRIS, JR., GUSSIE WELCH, RUBY FRANCIS FOWLER, MARY LOIS GREEN, JAMES THOMAS, LULA THOMAS and JANIE BUFORD,	*	
Plaintiffs,	*	**Case No:2:06-cv-956**
v.	*	
PACIFICARE LIFE AND HEALTH INSURANCE COMPANY, ROBERT D. BELL, ELIZABETH R. CLARK, WILLIE C. TILLIS, and Fictitious Defendants A through Z,	*	
Defendants.	*	

PLAINTIFFS' RESPONSE TO DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY IN OPPOSITION TO PLAINTIFFS' MOTION TO REMAND

COME NOW the Plaintiffs, by and through their undersigned counsel of record, and provide the following Response to Defendants' Notice of Supplemental Authority in Opposition to Plaintiff's Motion to Remand.

1. Defendants recently submitted a Notice of Supplemental Authority in Opposition to Plaintiff's Motion to Remand. (Court Doc. 28). At issue here is an Order dated August 7, 2007, in which the United States District Court for the Southern District of Alabama denied the plaintiffs' motion to remand in a similar fraud case involving another Medicare Advantage plan styled, *Della Dial v. HealthSpring of Alabama, Inc., CV-2:07-0412-KD-C*.

2. From a preliminary standpoint, the Order relied upon by the Defendants should not be considered at this time because the plaintiffs in *Dial* filed a Motion to Reconsider the Order on August 15, 2007. (See Court Doc. 22). The District Judge even entered an Order setting a briefing schedule on the plaintiffs' Motion to Reconsider, which has yet to run its course. (Court Doc. 23).

Because the *Dial* Court's ruling is still at issue, it should not be considered as supplemental authority at this time.

3. As to the substance of the *Dial* Order, the District Judge totally failed to analyze the critical second and third prongs of the preemption test set out in *Metropolitan Life Ins. Co. v. Taylor,* 481 U.S. 58, 107 S.Ct. 1542 (1987), which requires the federal law to "displace" the state law claim with a cause of action, much like ERISA and the LMRA. The *Dial* Court merely concluded that Congress intended for preemption and that an unspecified number of the plaintiffs' claims in their complaint fell within the areas that Congress intended to regulate. This analysis did not go far enough, as the *Dial* Court did take the final step critical for determining whether complete preemption exists.

According to the United States District Court for the Middle District of Alabama's analysis of *Taylor*, three factors have been identified in determining whether complete preemption exists. First is the intent of Congress. *See M.P. Means v. The Independent Life and Accident Ins. Co.*, 963 F.Supp. 1131, 1133 (M.D. Ala. 1997) (citations omitted). Second, "it is not sufficient that the federal law preempt the state law claim; the federal law must also 'displace' the state law claim with a cause of action. Third, the jurisdictional and enforcement provisions of ERISA and the LMRA must have a close parallel in the federal law at issue." *Id.* (citations omitted). Accordingly, even if there is evidence of clear intent on the part of Congress for the Medicare Act to preempt any state law causes of action (which there is not), one must also turn to "displacement" and an analysis of the civil enforcement schemes set out in ERISA and the LMRA to determine if complete preemption exists here.

An analysis of the language of the statutory provisions of the MMA, 42 C.F.R. §§422.560-422.612, compared to the civil enforcement schemes set out in ERISA, 29 U.S.C. §1132(a), and the LMRA, 29 U.S.C. §185, reveals that Congress did not create a federal civil enforcement scheme allowing for a cause of action that consumers can use to pursue their private rights against the HMO. A detailed examination of these statutory provisions shows that ERISA and the LMRA contain civil enforcement provisions expressly authorizing ERISA beneficiaries to bring actions to recover benefits under an ERISA plan and workers to bring actions to recover against labor organizations, respectively. In contrast, the MMA does not create an exclusive, federal cause of action vindicating a beneficiary's interest.

ERISA and the LMRA provide exclusive causes of action for the claim asserted and also set forth procedures and remedies governing that cause of action. Section 1132 of ERISA empowers a beneficiary to bring a civil action for relief against the plan provider. 29 U.S.C. §1132(a). There are mechanisms established for jurisdiction in federal court, removal to federal court and service of process. *Id.* at (e) and (h). ERISA also establishes mechanisms for the litigant to seek monetary awards, attorney fees, and awards for costs of action. *Id.* at (c) through (g). Likewise, the LMRA establishes precisely the same mechanisms for rights of action for civil suits against labor organizations. 29 U.S.C. §185.

There are no similar provisions in the MMA creating a cause of action that a Medicare Advantage enrollee can use to pursue their private claims against the HMO. The Defendants cite 42 C.F.R. §§422.560-422.612 and broadly claim that the Plaintiffs have administrative/grievance processes available to them to obtain a remedy directly from Pacificare. A close examination of this grievance and procedure process reveals, however, that there is no civil enforcement provision

whatsoever, much less one that parallels those under ERISA and the LMRA, as noted above. There is not a single provision allowing for the exclusive causes of action for claims asserted by an enrollee against the HMO like those under ERISA or the LMRA. Nor is there a single provision setting forth procedures and remedies governing that cause of action. Moreover, there is not a provision allowing for a private cause of action against the agent of the HMO who fraudulently misrepresented the Medicare Advantage plan. Consequently, in the removal context, the absence of any express remedial provision like those of ERISA and the LMRA defeats any complete preemption argument.

The above conclusion is consistent with federal precedent. *See M.P. Means v. Independent Life and Accident Ins. Co.*, 963 F.Supp. 1131 (M.D. Ala. 1997) (holding that, under the second and third prong of the *Taylor* preemption analysis, HIPPA did not preempt the plaintiffs state law claims because there was no evidence of a federal cause of action and jurisdictional grant of power like those found in ERISA and the LMRA); *see also Nott v. Aetna*, 303 F.Supp.2nd 565 (E.D. Penn. 2004) (holding that because the Medicare Act did not create an explicit or implied private right of action in federal court for HMOs to enforce their subrogation rights, there was no preemption by the Medicare Act); *Collins v. Baxter Healthcare Corp.*, 949 F.Supp. 1143 (D. N.J. 1996) (holding that even though the plaintiffs' claims were related to the Medicare Device Amendments Act, the Act did not preempt the state law claims because the federal statute did not provide a private right of action).

It is worth mentioning that the Defendants never assert that the MMA has the same civil enforcement scheme as that of ERISA or the LMRA. That is, the Defendants do not claim that the Medicare Act displaces a private right of action. The Defendants only argue that the Plaintiffs have

the opportunity to obtain a "remedy" from Pacificare through the administrative processes available under the MMA. There is the possibility that an enrollee can seek to have a claim reevaluated through the grievance and appeals process under the MMA. Even this remedy, however, pales in comparison to the remedies available under ERISA and the LMRA. Simply put, the MMA does not offer a monetary award, or the procedural means for achieving it, for an enrollee's tortious enrollment in the plan; and even if it did, the Plaintiffs are not claiming in this lawsuit that the Defendants have failed to properly pay a claim. As such, the grievance and appeals process is irrelevant for the purposes of this analysis.

Thus, in the context of preemption, it is not sufficient that the MMA establishes standards in the marketing and selling of Medicare Advantage plans that relate to the Plaintiffs' state law claims. It is also not sufficient that the MMA has some procedures and administrative processes in place for an enrollee to seek a remedy in certain situations. There must be a showing of clear Congressional intent for complete preemption; a clear showing of complete displacement of state law claims like those of ERISA and the LMRA; and a clear showing of a civil enforcement and jurisdictional scheme like those of ERISA and the LMRA. All of these factors must be met for there to be complete preemption. Even if one assumes that Congress intended for complete preemption (which it did not), there must be evidence of the second and third prong of the preemption analysis. That is, there must be evidence that the MMA has a civil enforcement scheme that parallels that of ERISA and the LMRA. Indeed, the Defendants have failed to offer even a shred of authority or evidentiary support for this critical part of the analysis.

Because the *Dial* Court failed to analyze the critical second and third prongs of the preemption test set out in *Taylor,* 481 U.S. 58, its Order denying remand in *Dial v. HealthSpring* is

inconsistent with U.S. Supreme Court precedent, as well as other federal precedent as shown above.

It is also worth mentioning that HealthSpring's Medicare Advantage plan ("Seniors First plan") in the *Dial* case did not contain an arbitration provision. By contrast, the "Secure Horizons" plan at issue in this case contains an arbitration provision. This distinction is significant. If the Medicare Act/MMA provided a civil enforcement scheme allowing for redress for wronged beneficiaries such as the Plaintiffs (as the Defendants would have this Court believe), the Defendants surely would not have inserted arbitration into their product. Because it did, Pacificare must have known, and even anticipated, that the Medicare Act/MMA did not have the jurisdictional authority or power to provide its customers adequate redress for complaints related to the "Secure Horizons" product.

4. Furthermore, even if one assumes that Congress did not intend for a state to impose its own marketing and sales regulations on Medicare Advantage products, this is where preemption ends. In other words, it should not be interpreted to mean that Congress intended to totally eradicate state tort law causes of action related to Medicare Advantage products. If it did, it is reasonable to assume that Congress would have provided for a civil cause of action that displaces a state law causes of action related to these plans. There is no such scheme here.[1]

The above conclusion is consistent with interpretative authority that followed the passage of the MMA in 2003. For example, the Rules and Regulations section of a publication of the

[1]State insurance regulations are much akin to the CMS/Medicare marketing regulations at issue in this case. There are numerous Alabama insurance regulations that regulate the sale and marketing of insurance products. At the same time, there are many state tort law causes of action that relate to the sale and marketing of insurance products. Even though these lawsuits arise from conduct that the State of Alabama intends to, and does in fact, regulate from a marketing and sales standpoint, state law tort claims are not preempted by these regulations. The reason is that the regulations do not displace a private cause of action.

Federal Register, which gives policy statements and interpretations of federal statutory rules, specifically addressed the extent of preemption in the field of Medicare Advantage plans and § 1395w-26(b)(3) of the MMA. While this specific section pertains to Part D prescription drug plans, the publication concludes that the same preemption laws apply to Medicare Advantage plans. It states:

> In areas where we have neither the expertise nor the authority to regulate, we do not believe that State laws would be superseded or preempted. For example, State environmental laws, laws governing private contracting relationships, **tort law,** labor law, civil rights law, and similar areas of law would, we believe, continue in effect and PDP sponsors in such states would continue to be subject to such State laws. Rather, our Federal standards would merely preempt the State laws in the areas where Congress intended us to regulate - such as the rules governing pharmacy access, formulary requirements for prescription drug plans, and marketing standards governing the information disseminated to beneficiaries by PDP sponsors.

70 Fed.Reg., No. 18, p. 4319 (January 28, 2005) (emphasis added) (attached hereto as Exhibit A). The Register echoes the same conclusion in a latter comment:

> *Comment:* One large insurer felt that our narrow interpretation of the statutory preemption authority was contrary to the language section of 1856(b)(3) of the Act. This insurer requested that CMS considered making clear that *all* State laws and regulations . . . are preempted with respect to MA and Part D plans.
>
> *Response:* As noted in the proposed rule, *we do not believe that either the principles of Federalism or the statute justify a broad preemption interpretation. Id.* At 4320 (emphasis added).

Based on the above statements, it is clear that preemption was not meant to cover state tort claims in connection with the sales and marketing practices of Medicare Advantage plans. Indeed, the Comment went to great lengths to point out the areas that it believes Congress intended Medicare to regulate: (1) the rules governing pharmacy access, (2) formulary requirements for prescription drug plans, and (3) marketing standards governing the information disseminated to beneficiaries by PDP sponsors. 70 Fed.Reg. 4319. First, the Plaintiffs are not a State and, thus, are not attempting

to impose State guidelines on the three areas mentioned above, much less impose more restrictive guidelines or rules that directly conflict. Secondly, none of the Plaintiffs' claims in the instant lawsuit pertain in any way to the rules governing pharmacy access, formulary requirements, or marketing guidelines for information disseminated to beneficiaries by PDP (prescription drug provider) sponsors. Although the Plaintiffs' claims are based on improper sales conduct by the agent, i.e., fraud and negligence, the Plaintiffs' state law claims are not attempting to impose additional or stricter marketing standards or guidelines for information disseminated by a Part D provider. Indeed, the Plaintiffs' state law claims do not impose or trigger any State standards in the area regulated whatsoever.

Moreover, commenting on preemption and the grievance procedures offered under the Medicare Act/MMA, the Federal Register has noted:

> In addition, we did not believe we would have the authority under Part D to set specific tort remedies or to govern resolution of private contracting disputes between plans and their subcontractors. We believe that the Congress did not intend for our regulations to supersede each other and every State requirement applying to plans - particularly those for which the Secretary lacks expertise and authority to regulate. Thus, we did not believe, for example, that wrongful death of similar lawsuits based upon tort law would be superseded by the appeals process established in these regulations . . . . Under principles of Federalism, and Executive Order 13132 on Federalism, which generally require us to construe preemption narrowly, we believe that an enrollee will still have State remedies available in cases in which the legal issue before the court is independent of an issue related to an organization's status as a stand alone PDP or MA-PD plan.

70 Fed.Reg., No. 18, 4362 (January 28, 2005) (attached hereto as Exhibit B). It is therefore clear that Congress did not intend for any grievance procedure offered under the Medicare Act to serve as a substitute for any private right of action, such as those asserted in the Plaintiffs' Complaint.

In addition to congressional intent, evidence of the CMS's intent with respect to preemption is instructive. Two bulletins issued by the Alabama Commissioner of Insurance, Walter Bell,

addressed the inappropriate marketing activities of Medicare Advantage producers in Alabama. In a bulletin dated February 16, 2006, which has already been placed at issue before this Court, Commissioner Bell stated:

> [S]tate law and regulatory provisions regarding producer activity apply to the marketing of Medicare Part D . . . . CMS will refer complaints it receives about producers licensed in this state to the Alabama Department of Insurance. This bulletin reminds licensed producers that they are subject to all laws and regulations of this state, including those relating to the duty of good faith and fair dealing, the suitability of sale, and the prohibitions against misrepresentations, churning, and high pressure sales tactics . . . . **Any proven misconduct will be prosecuted under the laws of this state.** (AL Insurance Bulletin 2-16-2006, Medicare Part D Marketing, attached hereto as Exhibit C) (emphasis added).

Again, while this bulletin specifically addressed the marketing of Medicare Part D, it relates to the cross-selling of Medicare Advantage plans. Thus, sales and marketing conduct related to Medicare Advantage plans is directly implicated in this bulletin.

Moreover, the Alabama Department of Insurance issued another bulletin on June 8, 2007, which specifically addressed the marketing of Medicare Advantage plans. The bulletin set forth conditions for the marketing of these plans. In addition, the bulletin stated, "The four conditions set forth above are in addition to any other requirements set out in Alabama Department Regulation, Chapter 482–1-071." (AL Insurance Bulletin 6-8-2007, Medicare Advantage Insurance Producers, attached as Exhibit D). Notably, chapter 482-1-071 of the Alabama Administrative Code sets forth state standards for marketing of these products.

Therefore, in light of the recent actions and comments of federal and state agencies, *viz.* the CMS and the Alabama Insurance Commissioner, it is clear that the intent of the preemption section of the statute was not to preempt state causes of action arising from improper sales and marketing conduct. This matter should, therefore, be remanded to state court on this basis, in addition to the

fact that there is no civil enforcement scheme within the Medicare Act/MMA that displaces the Plaintiffs' state law claims with a private right of action like those found in ERISA and the LMRA.

WHEREFORE, PREMISES CONSIDERED, the Plaintiffs respectfully request this Court to remand this matter to state court from where it was removed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 30th day of August, 2007, I electronically filed the foregoing with the Clerk of the United States District Court, Middle District of Alabama using the CM/ECF system, which will send notification of such filing to the following:

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Exhibit

A

required to comply with the solvency standards established by us. In the event the State ultimately denied the application, we stated that we could extend the waiver through the contract year as we deemed appropriate to provide for transition.

In the final rule we have clarified, with the addition the distinctions between the temporary waiver (for regional plans) and the waiver for entities seeking to offer a plan in a single State, the timeline for processing the application for the waiver and the length of the waiver itself. Thus in new § 423.415(c) we clarify that Secretary will determine the time period appropriate for the processing of the application and in new § 423.415(d), we repeat the policy of the proposed rule that in no case will the temporary waiver extend beyond the end of the calendar year.

4. Solvency Standards for Non-Licensed Entities (§ 423.420)

In proposed § 423.420, we specified that sponsors that have been granted a waiver by us must maintain reasonable financial solvency and capital adequacy.

Solvency standards have been developed after statutorily required consultation with the National Association of Insurance Commissioners. These standards are undergoing internal CMS review. We anticipate that these standards, which are required to be published by January 1, 2005 will be published on the CMS website in the near future in conjunction with the initial application forms for PDP organizations. These solvency standards will include such items as required minimum net worth and liquidity requirements as well as reporting requirements for future PDPs who have received waiver of State licensure. We are adopting the policy we proposed for reasonable financial solvency and capital adequacy in this final rule.

5. Preemption of State Laws and Prohibition of Premium Taxes (§ 423.440)

In the August 4, 2004 proposed rule, we stated that we would implement section 1860D–12(g) of the Act at proposed § 423.440(a), by specifying that to the extent there are Federal standards, those standards supersede any State Law.

We proposed that for purposes of Part D, with the exceptions of State licensing laws or State laws related to plan solvency, State laws would not apply to prescription drug plans and PDP sponsors.

The proposed rule for the Medicare Advantage program also discussed preemption of State laws, and because Part D and Part C incorporate the same preemption laws at section 1856(b)(3) of the Act, we believe it is necessary to summarize those discussions in this final rule.

In the Medicare Advantage proposed rule, we noted that prior to enactment of the MMA, section 1856(b)(3) of the Act provided for two types of preemption: general and specific. The presumption was that a State law was not preempted if it did not conflict with an M+C requirement, and did not fall into one of the four specified categories where preemption was presumed. (These four categories were: benefit requirements, including cost-sharing rules; requirements relating to the inclusion or treatment of providers; requirements concerning coverage determinations and related appeals and grievance processes; and requirements relating to marketing materials and summaries and schedules of benefits concerning M+C plans.)

We concluded that the MMA reversed this presumption and provided that State laws are presumed to be preempted unless they relate to licensure or solvency. We also referenced the Congress' intent that the MA program, as a Federal program, operate under Federal rules, and referred to the Conference Report of the MMA as making clear the Congress' intent to broaden the scope of preemption through its change to section 1856(b)(3) of the Act. See 69 FR 46866, 46904. We believe that because the Congress incorporated the same preemption standard into the Part D program, and because the Congress required the preemption rules to apply consistently in Parts C and D, this same reasoning would apply to Part D.

In addition, in the proposed rule for Part D, we stated that although the Congress included broad preemption rules in section 1856(b)(3) of the Act, we did not believe that the Congress intended for each and every State requirement applying to PDP sponsors to become null and void. Specifically, we stated:

> In areas where we have neither the expertise nor the authority to regulate, we do not believe that State laws would be superseded or preempted. For example, State environmental laws, laws governing private contracting relationships, tort law, labor law, civil rights laws, and similar areas of law would, we believe, continue in effect and PDP sponsors in such States would continue to be subject to such State laws. Rather, our Federal standards would merely preempt the State laws in the areas where the Congress intended us to regulate—such as the rules governing pharmacy access, formulary requirements for prescription drug plans, and marketing standards governing the information disseminated to beneficiaries by PDP sponsors. We believe this interpretation of our preemption authority is in keeping with principles of Federalism, and Executive Order 13132 on Federalism, which requires us to construe preemption statutes narrowly. (69 FR 46696.)

We also recognized that while the Congress specifically stated that State licensure and solvency laws would not be preempted, this did not mean that States could condition licensure on a sponsor meeting requirements unrelated to what we would consider licensure requirements. We also addressed this issue in the Medicare Advantage proposed rule, explaining:

> We believe that the exception for State laws that relate to "State licensing" must be limited to State requirements for becoming State licensed, and would not extend to any requirement that the State might impose on licensed health plans that-absent Federal preemption-must be met as a condition for keeping a State license. If a State requirement could be considered to relate to State licensing simply because the State could revoke a health plan's license for a failure to meet the requirement, this would mean that States could impose virtually any requirement they wished to impose without the requirement being preempted. ... Because we believe that it is clear that the Congress intended to broaden the scope of Federal preemption, not to narrow it, we also believe that the exception for laws relating to State licensing must be limited to requirements for becoming State licensed (such as filing articles of incorporation with the appropriate State agency, or satisfying State governance requirements), and not extended to rules that apply to State licensed health plans. (69 FR 46904.)

We are adopting these preemption interpretations as our final policy. We also note that in the accompanying regulation text we have replaced PDP sponsor with Part D sponsor, as we believe that the preemption of State law and the prohibition against imposition of premium taxes should operate uniformly for all Part D sponsors. We note that licensure requirements in this Part continue to apply only to PDP sponsors, as other Part D sponsors (such as MA organizations and cost-based HMOs and CMPs) are subject to their own licensing laws.

Comment: One large insurer felt that our narrow interpretation of the statutory preemption authority was contrary to the language of section 1856(b)(3) of the Act. This insurer requested that CMS consider making clear that all State laws and regulations (with the exception of State licensing and solvency laws) are preempted with respect to MA and Part D plans.

Response: As noted in the proposed rule, we do not believe that either the

principles of Federalism or the statute justify such a broad preemption interpretation. We do not believe, for example, we could preempt all State environmental or civil rights laws, nor do we believe it was the Congress' intent to do so. The preemption in section 1860D–12(g) of the Act is a preemption that operates only when CMS actually creates standards in the area regulated. To the extent we do not create any standards whatsoever in a particular area, we do not believe preemption would be warranted.

Comment: A pharmaceutical manufacturer and a pharmaceutical manufacturing association requested clarification from us that it is not our intent to preempt any State pharmacy laws dealing with the practice of therapeutic substitution.

Response: In general, we do not think we have the authority to preempt State pharmacy licensing laws dealing with the practice of therapeutic substitution and we do not intend to establish standards in this area. However, it should be noted that the forthcoming electronic prescription standards do have the potential to impact State pharmacy practices and such standards could preempt State pharmacy practice laws and regulations that conflict with them.

We are adopting the requirements of the proposed rule with the technical and clarifying changes noted throughout this preamble. We are also adopting the premium tax prohibition included in the proposed without modification. Both rules are found at § 423.440

J. Coordination Under Part D Plans with Other Prescription Drug Coverage

Proposed subpart J set forth the application of Medicare Part D rules to Medicare Part C plans; established waivers for employer-sponsored group prescription drug plans, MA-PD plans, cost plans, and PACE organizations; and established requirements for coordination of benefits with State Pharmaceutical Assistance Programs (SPAPs) and other providers of prescription drug coverage.

Below we summarize the proposed provisions of subpart J and respond to public comments. (Please refer to the August 2004 proposed rule (69 FR 46696) for a detailed discussion of our proposals.)

1. Overview and Terminology (§ 423.454)

Subpart J implemented sections 1860D–2(a)(4), 1860D–2(b)(4)(D), 1860D–11(j), 1860D–21(c), 1860D–22(b), 1860D–23(a), 1860D 3(b), 1860D–23(c), 1860D–24(a), 1860D–24(b), and 1860D–24(c) of the Act, as added to the Act by section 101(a) of the MMA. We proposed that, in general, the requirements of Part D generally apply under Part C for prescription drug coverage offered by MA-PD plans, although certain waivers are available. In addition, we implemented section 1860D–22(b) of the Act at proposed § 423.458(c) providing us the authority to waive the requirements of this part for employer-sponsored group prescription drug plans.

a. Part D Plans

Unless otherwise indicated, references to "Part D plans" in the proposed rule referred to any or all of MA-PD plans, prescription drug plans (PDPs) and fallback prescription drug plans. Likewise, the term "Part D plan sponsor" referred to MA organizations offering MA-PD plans, PDP sponsors, and eligible fallback entities offering fallback plans. We have moved the definition of "Part D plan" to § 423.4 of our final rule and expanded the definition such that it includes cost plans and PACE organizations offering qualified prescription drug coverage. Similarly, we have revised the definition of "Part D sponsor" under § 423.4 of our final rule to include cost plans and PACE organizations offering qualified prescription drug coverage.

b. Employer-sponsored Group Prescription Drug Plan

We used the term "employer-sponsored group prescription drug plan" to mean a prescription drug plan under a contract between a PDP sponsor or MA organization offering an MA-PD plan and employers, labor organizations, or the trustees of funds established by one or more employers or labor organizations (or combination thereof) to furnish prescription drug benefits under employment-based retiree health coverage.

c. State Pharmaceutical Assistance Program (SPAP)

We defined an SPAP, for purposes of this part, as a program operated by or under contract with a State if it:

(1) Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;

(2) Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;

(3) Meets the benefit coordination requirements specified in this part; and

(4) Does not change or affect the primary payer status of a Part D plan.

Comment: Although one commenter supported our proposed definition of the term "SPAP," several commenters urged us to allow SPAPs to endorse one or more Part D plans for SPAP enrollees. They believe that the non-discrimination criteria contained in the definition of the term SPAP should be designed to maximize the efficiency and effectiveness of offering benefits that supplement the benefits available under Part D coverage to enrollees. Some of these commenters believe that a preferred plan approach, if accomplished via a competitive bid process, supports the competitive, market-based model that the Congress envisioned. One commenter stated that such an approach would help it to "ratchet down" administrative costs. Another commenter asserted that the statute does not prohibit a State from providing consumer advice to its SPAP enrollees regarding which Part D plan might work best with an SPAP or offer the best value.

Commenters believe that this interpretation is consistent with the intent to establish an effective coordination mechanism between SPAPs and Part D plans. Defining non-discrimination in a way that prohibits SPAPs from designating preferred Part D plans and prohibiting auto-enrollment of SPAP beneficiaries into preferred plans would not facilitate enrollment in Part D plans and would further complicate, rather than promote, coordination between Part D plans and SPAPs.

Response: Section 1860D–23(b)(2) of the Act defines an SPAP, in part, as a program that "in determining eligibility and the amount of assistance to Part D enrollees, provides assistance to such individuals in all Part D plans and does not discriminate based upon the Part D plan in which the individual is enrolled." We are interpreting the non-discrimination language in section 1860D–23(b)(2) of the Act and § 423.464(e)(1)(ii) of our final rule to mean that SPAPs, if they offer premium assistance or supplemental assistance for Part D cost sharing, must not only offer equal assistance to beneficiaries enrolled in all Part D plans available in the State, but also may not steer beneficiaries to one plan or another through benefit design or otherwise. We believe that the law intends that all Part D plans in a State be given comparable opportunities. Requiring States to coordinate with all Part D plans, without discrimination, levels the playing field for Part D plans that want to provide benefits in a particular State.

We further interpret section 1860D–23(b)(2) of the Act as prohibiting SPAPs from automatically enrolling ("auto-enrolling") beneficiaries into a preferred

Exhibit

B

8. Federal Preemption of Grievances and Appeals

Section 232(a) of the MMA amended section 1856(b)(3) of the Act so that it now reads: "The standards under this part shall supersede any State law or regulation (other than State licensing laws or State law relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part." Section 1860D–12(g) of the Act then incorporates this preemption rule for plans.

We believe that the grievance procedures for the Part D Drug Program under Title I must be the same as those that apply to the MA program under Title II. In the proposed rule, we proposed continuing to defer to State law on the issue of authorized representatives of enrollees in the appeals process.

We did not believe that the Congress intended for the Secretary to regulate matters for which the Secretary was not authorized to promulgate standards (for example, spousal rights, powers of attorney, or legal guardianship). Often, authorized representative matters are non-Federal issues. However, because we do have the authority to regulate in the field of grievances, we were concerned that State grievance requirements would now be preempted, thereby requiring us to reexamine our Federal grievance requirements. We requested comments on this preemption issue and the specific State grievance requirements that should be incorporated into Federal regulatory requirements at § 423.564.

We also noted that tort law, and often contract law, are generally developed based on case law precedents established by courts, rather than by legislators through statutes or by State officials through regulations. In addition, we did not believe we would have the authority under Part D to set specific tort remedies or to govern resolution of private contracting disputes between plans and their subcontractors. We believed that the Congress did not intend for our regulations to supersede each and every State requirement applying to plans—particularly those for which the Secretary lacks expertise and authority to regulate. Thus, we did not believe, for example, that wrongful death or similar lawsuits based upon tort law would be superseded by the appeals process established in these regulations. Similarly, State contract law would continue to govern private contract disputes between plans and their subcontractors.

Under principles of Federalism, and Executive Order 13132 on Federalism, which generally require us to construe preemption narrowly, we believe that an enrollee will still have State remedies available in cases in which the legal issue before the court is independent of an issue related to the organization's status as a stand alone PDP or an MA-PD plan.

Comment: We solicited comments on whether the proposed Federal grievance procedures should preempt State grievance requirements. We received several comments on this issue, which primarily supported adopting a single set of grievance procedures to reduce enrollee confusion and plan burden. Some commenters recommended that we adopt the provisions proposed by us for Medicare+Choice organizations in a January 24, 2001 proposed rule. See 66 FR 7,593. However, one commenter opposed Federal law preempting State law where Part D appeals are concerned.

Response: We agree with the commenters that establishing a uniform set of grievance standards will reduce confusion and burden for enrollees and plans. We also believe that one set of rules will ensure better beneficiary protections and achieve consistency among plan operations. Thus, § 423.564 implements the specific guidelines for Part D grievances that we proposed in January 2001 for Medicare+Choice organizations. We disagree with the commenter that Federal provisions should not preempt State requirements for appeals. We believe that such an approach is inconsistent with § 232(a) of the MMA, which preempts State appeal and grievance requirements and which is incorporated into the Part D laws through section 1860D–12(g) of the Act.

Under the grievance requirements, plans must notify enrollees of decisions as expeditiously as the enrollee's case requires, but no later than 30 calendar days after receiving a complaint. Plans may extend the timeframe by up to 14 calendar days if the enrollee requests the extension, or if the plan justifies a need for additional information and the delay is in the interest of the enrollee. We believe that the timeframes must be according to the enrollee's case as opposed to the enrollee's health since not all grievances involve medical care. For example, an enrollee may complain that a network pharmacy does not offer convenient hours for getting prescriptions filled. In addition, we believe that most plans will be able to respond to most grievances within 30 days. If an enrollee makes a grievance orally, the plan may respond to it orally or in writing, unless the enrollee requests a written response. If an enrollee files a written grievance, then the plan must respond in writing. In addition, a plan must provide information to enrollees on their right to request a review by a Quality Improvement Organization (QIO) if the grievance involves a quality of care issue. For any complaint involving a QIO, the plan must cooperate with the QIO in resolving the complaint. Plans must establish a 72-hour expedited grievance process for complaints involving certain procedural matters in the appeals process. Finally, plans must create a system to track and maintain records on all grievances.

We note that under MMA, enrollees will still have access to various State remedies available in cases in which an issue is unrelated to the plan's status as a PDP or MA-PD plan.

9. Employer Sponsored Prescription Drug Programs and Appeals

As explained above, MA-PDs and PDPs are subject to the requirements of Part 423 for Part D benefits. In addition, when an employer, whether by contracting with an MA-PD, PDP, or otherwise, provides prescription drug benefits in addition to those covered under Part C and Part D of Title XVIII of the Act to their retirees, such employer may have established a group health plan governed by both Title I of the Employee Retirement Income Security Act of 1974, as amended (ERISA), and State law (to the extent such State law is not preempted by ERISA).

In drafting our Part C, MA rules, we consulted the Department of Labor (DOL), employer groups, and the health plan industry in trying to eliminate unnecessary Federal regulation of claims and appeals issues that impact matters within the jurisdiction of both DOL and DHHS. Based on our experience under Part C, we have reason to believe that some Medicare eligible individuals may receive integrated prescription drug benefits, that is, Part D benefits through an MA-PD or PDP and supplemental benefits through an ERISA-covered plan. For example, an ERISA-covered plan could pay all or part of the retiree's cost sharing amount (for example, deductibles and coinsurance amounts specified in subpart C of Part 423) for a covered Part D drug provided through an MA-PD or PDP. Clearly, if the enrollee had a dispute about Part D coverage, he or she could file an appeal under the provisions in subpart M of Part 423. If the enrollee's dispute involved only the amount of cost sharing paid by the ERISA plan, he or she would file an appeal in accordance with the

Exhibit

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BULLETIN

TO: All Insurers Licensed in Alabama

FROM: Walter A. Bell, Commissioner of Insurance

DATE: February 16, 2006

RE: Medicare Part D Marketing

Since October 1, 2005, marketing activity for the new Medicare prescription drug benefit, Medicare Part D, has been permissible. According to the Centers for Medicare & Medicaid Services (CMS), only state-licensed insurance producers may engage in marketing activity. The Medicare Modernization Act does not preempt producer licensing laws. Thus, state law and regulatory provisions regarding producer activity apply to the marketing of Medicare Part D.

CMS has received complaints about alleged misconduct by licensed producers with regard to Medicare Part D marketing. CMS will refer complaints it receives about producers licensed in this state to the Alabama Department of Insurance. This bulletin reminds licensed producers that they are subject to all laws and regulations of this state, including those relating to the duty of good faith and fair dealing, the suitability of sale, and the prohibitions against misrepresentation, churning, and high pressure sales tactics.

We view with a high degree of skepticism the use of a lead relating to Part D marketing activity to cross-sell other insurance products of any type. The new Part D benefit is fundamentally confusing for the Medicare beneficiary. It would be unwise for the producer to take advantage of the Part D lead to sell other insurance products to a Medicare beneficiary for which he or she may not be suited.

Allegations of misconduct related to Part D marketing will be thoroughly investigated by this office. Any proven misconduct will be prosecuted under the laws of this state relating to producer licensing.

WAB/EB/bc

Exhibit

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BULLETIN

TO: All Medicare Advantage Companies

FROM: Walter A. Bell, Commissioner of Insurance

DATE: June 8, 2007

RE: Medicare Advantage Insurance Producers

It has come to the attention of the Department some Medicare Advantage insurance producers are marketing and soliciting Alabama senior citizens in a deceptive and inappropriate manner. In some cases the agent has provided a business card that was designed so as to give the appearance the agent represents Medicare.

Therefore, all insurance producers marketing Medicare Advantage in this state must do the following:

1. Each insurance producer must leave an identifying card with the insured.

2. This card must only represent that the producer is an insurance agent and may identify the insurance company said producer represents.

3. The insurance producer may not under any circumstances say, do, or leave any materials including a business card that would cause a prospective buyer to misunderstand the organization the producer represents.

4. No check for the Medicare Advantage product may be made out to any named entity other than the insurance company.

The four conditions set forth above are in addition to any other requirements set out in Alabama Department Regulation, Chapter 482-1-071.

WAB/EB/ss